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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

DORIS JONES and ALFRED JONES, a married couple,

Plaintiffs,

v.

C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation,

Defendants.

No. 2:15-MD-02641-DGC

DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT OF PLAINTIFFS DORIS AND ALFRED JONES'S CLAIMS

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

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MOTION

Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1, and Case Management Order No. 23 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court for partial summary judgment as to certain of Plaintiff Doris Jones's product liability claims (Counts II, VII, VIII, IX, XII) and her claim for punitive damages as alleged in Plaintiff's Short Form Complaint (2:16-cv-00782-DGC, Doc. 1). Plaintiffs have withdrawn claims for manufacturing defect (Counts I and V), Negligent Failure to Recall/Retrofit (Count VI), Breach of Express Warranty (Count X), and Breach of Implied Warranty (Count XI). For the reasons stated below, Bard is entitled to judgment as a matter of law as to certain other claims asserted by the plaintiff.

This motion is supported by Defendants' Memorandum of Points and Authorities and Separate Statement of Facts ("SSOF") which are filed herewith.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

Plaintiff Doris Jones brings this product liability action for damages she claims to have suffered as a result of complications allegedly experienced related to a Bard Eclipse® inferior vena cava filter, a prescription medical device that was placed in her inferior vena cava ("IVC") after [redacted] (the "Filter"). Plaintiff claims that the Filter was defective because, [redacted] Notably, fracture is a well-known and accepted potential complication with all IVC filters (including with the Filter), given the life-saving nature of these devices. Indeed, Ms. Jones's implanting physician testified that he was well-aware of these potential complications before placing the Filter, and did not recall ever reading the Filter's Instructions for Use ("IFU") because he was already familiar with the risks.

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Bard moves for partial summary judgment under Federal Rule of Civil Procedure 56 on the following grounds:[1]

A. Plaintiff's failure-to-warn (Counts II, VII) and misrepresentation (Counts VIII, XII) claims fail because Plaintiff has failed to provide any evidence that the implanting physician ever read the Eclipse IFU. Furthermore, Bard provided adequate warnings of the complications experienced by Plaintiff and any alleged failure to warn by Bard was not the proximate cause of Plaintiff's injuries.

B. Plaintiff's consumer fraud claim (Count XIV) fails because Plaintiff has not provided any evidence that that the implanting physician received any misrepresentation or relied on any misrepresentation.

C. Plaintiff's negligence *per se* claim (Count IX) fails because Plaintiff has not provided any evidence that Bard violated a state safety statute and any alleged violation of the FDCA would be preempted by federal law.

D. Plaintiff's punitive damages claim fails because there is no evidence that such are warranted.

II. Statement of Undisputed Facts.

Plaintiff Doris Jones underwent [redacted] (SSOF ¶ 1.) The Filter is sold to medical facilities, not directly to doctors or patients. (*Id.* at ¶ 2.)

[redacted] (*Id.* at ¶ 3.)

[redacted]

[1] Bard met and conferred extensively with counsel for Ms. Jones prior to filing this motion. Counsel represented that they were going to continue pursuing all of the claims addressed in this motion.

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[redacted] (*Id.* at ¶ 4.) [redacted] (*Id.* at ¶ 5.) [redacted] (*Id.* at ¶ 6.)

In August 2010, Ms. Jones again [redacted] (*Id.* at ¶ 7.) [redacted] (*Id.*) [redacted] (*Id.* at ¶ 8.) [redacted] (*Id.* at ¶ 9.) [redacted] (*Id.* at ¶ 10.) [redacted] (*Id.*)

Dr. Avino testified that he does not recall ever reading the IFU. (*Id.* at ¶ 12.) However, he explained that he was generally familiar with IVC filter IFUs, the risks inherent with all IVC filters such as fracture, migration, perforation, and tilt, and began implanting IVC filters during his residency, 20 years before he implanted Ms. Jones' filter. (*Id.* at ¶ 13.) Although there is no evidence that Dr. Avino read the IFU, which was reviewed by the FDA as a part of the clearance process, it specifically identifies fracture and embolization as known risks of the Filter. (*Id.* at ¶ 14.)

Five years later, Ms. Jones [redacted] (*Id.* at ¶ 17.) [redacted] (*Id.* at ¶ 18.) [redacted]

[redacted] (*Id.* at ¶ 19.) [redacted]

[redacted] (*Id.* at ¶ 20.) [redacted]

[redacted]

[redacted]

[redacted] (*Id.*)

III. Summary Judgment Standard.

Summary judgment is appropriate upon showing that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see Jesinger v. Nev. Fed. Credit Union*, 24 F.3d 1127, 1130 (9th Cir. 1994). Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *Southern Calif. Gas. Co. v. City of Santa Ana*, 336 F.3d 885, 888 (9th Cir. 2003).

IV. Georgia Substantive Law Applies.

Georgia substantive law governs Plaintiff's common-law claims. Although Plaintiff filed her complaint directly in the MDL, she identified Georgia in her Short Form Complaint as the forum in which venue would be proper absent direct filing, (2:16-cv-00782-DGC, Doc. 1), so Georgia's conflict-of-law rules apply. (*See* Doc. 1485). Georgia follows the *lex loci delicti* doctrine, which applies the substantive law of the place of injury. *See Coon v. Med. Ctr., Inc.*, 300 Ga. 722, 730, 797 S.E.2d 828, 834 (2017). The place of injury here is Georgia because "at least a substantial amount, if not all, of the injuries allegedly caused by the [filter's] alleged defects occurred in Georgia. Therefore, because 'the last event . . . necessary to make [Defendants] liable for the alleged tort[s]' likely occurred in Georgia, the Court applies Georgia law." *See Schmidt v. C. R. Bard, Inc.*, No. 6:14-CV-62, 2014 WL 5149175, at *2 (S.D. Ga. Oct. 14, 2014) (applying Georgia substantive law under *lex loci delicti* despite plaintiff being implanted with medical device in Michigan).

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V. Argument and Citation of Authority.

A. Plaintiff's Failure-to-Warn (Counts II, VI) and Misrepresentation (Counts VIII, XII) Claims Fail Because There Is No Evidence Dr. Avino Read the IFU, and Bard Provided Adequate Warnings and/or Any Alleged Failure to Warn Could Not Be the Proximate Cause of Plaintiff's Injuries.

1. Plaintiff Has Failed to Provide Any Evidence That Dr. Avino Read the IFU.

Plaintiff's failure-to-warn and misrepresentation claims fail[2] because Ms. Jones's implanting physician, Dr. Avino, did not read the IFU. It is well settled under Georgia law that "[u]nder the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities." *McCombs v. Synthes*, 277 Ga. 252, 253, 587 S.E.2d 594 (2003) (internal citations omitted); *see also*, *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1277–81, 1281 (11th Cir. 2002) (per curiam).

"[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk." *Wilson Foods Corp. v. Turner*, 218 Ga. App. 74, 75, 460 S.E.2d 532, 534 (1995). Here, Plaintiff cannot prove that any warning inadequacy was the proximate cause of her injuries because she cannot prove that Dr. Avino ever read the IFU:

Q. Do you know if you ever read the IFU for the Eclipse IVC filter?

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[2] Under Georgia law, there are "no misrepresentation claims for products liability distinct from failure to warn claims." *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM, 2016 WL 4844442, at *11 (N.D. Ga. Mar. 24, 2016). Accordingly, Plaintiff's negligent and fraudulent misrepresentation claims (Counts VIII, XII) "collapse into the failure to warn claims," and fail for the same reasons. *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008).

A. Not that I recall.

(SSOF, ¶ 12.) As a result, Plaintiff's failure to warn claim should be dismissed. *See In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig.*, 127 F. Supp. 3d 1306, 1360 (N.D. Ga. 2015) ("[The implanting physician] does not recall reading a product insert, and its warnings, that accompanied any hip replacement device he has implanted. As a result of his personal practices, the undisputed evidence is that [the implanting physician] did not and would not have read the insert warnings that were provided with the device implanted to replace Plaintiff's right hip. As a result, the evidence here does not support a failure to warn claim based on the warning provided for the implant at issue in this case, even if the warning was defective.") (applying Utah law but citing various jurisdictions in which a prescribing physician's failure to read the product warning broke the chain of causation) (citations omitted).

Moreover, Plaintiff's failure to warn claim lacks proximate causation for a second, independent reason: Dr. Avino had actual knowledge of the risk of fracture. Instead of reading the Eclipse IFU, Dr. Avino was "generally familiar with IVC filter IFUs, if they warn of things like fractures, migration, perforation, tilt; complications like that," and began implanting IVC filters during his residency, 20 years before he implanted Ms. Jones' filter. (SSOF, ¶ 13.) *See Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1363 (N.D. Ga. 1999) (concluding that "[r]egardless of the sufficiency or insufficiency of the warnings at issue here, Plaintiff still cannot recover. Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link is broken and the plaintiff cannot recover."); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1277–78, 1281 (11th Cir. 2002) (per curiam) (finding that manufacturer adequately warned doctors and nurses of risks of third-party activation of morphine pump because evidence demonstrated the doctors and nurses all had actual knowledge of risk).

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2. Even If Dr. Avino Read the IFU, the Warning Was Adequate Because It Warned of the Precise Risk Experienced by Plaintiff.

Under the learned intermediary doctrine, a manufacturer discharges its duty to warn by apprising the prescribing physician of potential dangers that may result from the device's use. *Hawkins*, 147 Ga. App. at 483, 249 S.E.2d at 288; *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 (11th Cir. 2002) ("Ellis also suggests that, even if the learned intermediary rule applies, there was a jury issue regarding the sufficiency of the warnings given by the defendants to the learned intermediaries in this case. We disagree. As the district court noted, defendants presented evidence that, through Bimeco, it warned the physicians and nurses at GBMC that only the patient should press the activation button unless a doctor ordered otherwise."). If the warning provided to the learned intermediary is adequate, the plaintiff cannot recover. *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010).

Here, Bard had a duty to warn Dr. Avino of the risks of its use. Even though Dr. Avino could not recall ever reading the Eclipse IFU, it contains specific warnings regarding the risk of filter fracture, the complication experienced by Ms. Jones. Under the bolded heading "**Warnings**," the IFU reads:

> - Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.

(SSOF, ¶ 14.) This warning is repeated under the bolded heading "**Potential Complications**", which also adds that:

> **All of the above complications have been associated with serious adverse events such as medical intervention or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ration for a patient who is at risk of pulmonary embolism without intervention.**

(*Id.* at ¶ 15.) (emphasis in original). Furthermore, the "Clinical Experience" section notes the number of fracture observed during the clinical study of one hundred patients. (*Id.* at ¶

16.). Because the IFU contained warnings regarding the relevant risks of using the Filter, Bard's warnings were adequate. *See Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 (11th Cir. 2002); *Presto v. Sandoz Pharm. Corp.*, 226 Ga. App. 547, 548, 487 S.E.2d 70, 73 (1997) ("a warning as to possible danger in [the prescription product's] use to the prescribing physician is sufficient").

Moreover, Bard cannot be liable for failure to warn of the complications with the Filter experienced by Ms. Jones because those complications are well-known by medical professionals. Where a product is sold to a particular group or profession, the manufacturer is not required to warn against risks generally known to such group or profession. *Exxon Corporation v. Jones*, 209 Ga. App. 373, 375, 433 S.E.2d 350 (1993) (quoting *Eyster v. Borg-Warner Corp.*, 131 Ga. App. 702, 704, 206 S.E.2d 668 (1974)); *see Ellis*, 311 F.3d at 1277–78, 1281. Accordingly, even had the IFU not provided the necessary warnings, which Bard denies, Bard could not be liable for failure to warn of the complications experienced by Ms. Jones because they were widely known, and well-documented, by the medical community. (SSOF at ¶¶ 21-23.) Indeed, Plaintiff's expert acknowledges that *all* IVC filters are known to have complications, including filter fracture, migration, tilt, and perforation and Plaintiff's biomedical engineering expert testified it is impossible to design an IVC filter that never tilts, fractures, migrates, or perforates. (*Id.*) Because the relevant risks involved in implanting the Filter were well-documented and well-known to medical professionals, Bard cannot be liable for any failure to warn of those risks. *See Ellis*, 311 F.3d at 1279-80.

Plaintiff likely will assert that Bard was obligated to warn that the Filter may have been more likely to fail than other IVC filters. However, Bard can find no Georgia law creating a duty on a manufacturer to provide comparative rates of complication for its product to other similar products on the market. Indeed, Georgia law does not require a manufacturer to provide comparative rates of complication for its products. *See Hoffman v. AC&S, Inc.*, 248 Ga. App. 608, 610, 548 S.E.2d 379, 382 (2001) (noting under Georgia law, "a manufacturer has the absolute right" to have his strict liability for injuries

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adjudged on the basis of "his own marketed product and not that of someone else."); *see also Dixie Grp., Inc. v. Shaw Indus. Grp., Inc.*, 303 Ga. App. 459, 463, 693 S.E.2d 888, 892 (2010) (same). And, courts from other jurisdictions that have addressed the issue have found that pharmaceutical and medical-device manufacturers have no such duty to warn. *See, e.g., Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 291–92 (6th Cir. 2015) (affirming summary judgment on failure to warn claim where the lower court rejected the plaintiff's argument that the product labeling did not warn that the risk of stroke for the birth control at issue was higher than with other birth control products); *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990) ("The manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug . . . . It is not obligated to provide a comparison of its drug with others").[3] Likely for this reason, Bard could find no IVC filter manufacturer that provides comparative rates in the instructions for use that it provides to doctors. *See* Competitor IFUs (not including any comparative rate information), attached as Exhibit A. Accordingly, summary judgment is

[3] *See also Smith ex rel. Smith v. Wyeth Labs., Inc.*, No. CIV.A. 84-2002, 1986 WL 720792, at *9–10 (S.D. W. Va. Aug. 21, 1986) (rejecting argument that defendants had a duty to warn of adverse reaction rates as compared to competitor products, noting there is "no authority for the proposition that a drug manufacturer has a duty to warn prescribing physicians of the rate of adverse reactions" and "no authority for [the plaintiffs'] argument that a drug manufacturer may be required to represent that other drugs with similar effects are safer," and "[a]s a practical matter, this would extremely difficult, perhaps impossible . . . ."); *Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060, 1064 (W.D. Okla. 1987) (finding defendant's warning label on its DTP vaccine adequate as a matter of law and quoting Smith); *Pluto v. Searle Lab.*, 690 N.E.2d 619, 621 (Ill. App. Ct. 1997) (finding a pharmaceutical manufacturer "is under no duty to provide information on other products in the marketplace"); *Cowart v. Avondale Indus., Inc.*, 792 So. 2d 73, 77 (La. Ct. App. 2001), writ denied 805 So. 2d 211 (rejecting plaintiff's argument that defendant manufacturer owed a duty to plaintiff to make him aware of safer alternative products and reversing lower court's denial of summary judgment); *Hain v. Johnson & Johnson* (N.J. Super. Ct. June 13, 2013) ATL-L-8568-11 MT (granting summary judgment to defendant pharmaceutical manufacturer and rejecting plaintiff's argument that label was inadequate due to its failure to disclose that studies showed higher tendon toxicity in defendant's drug compared to other like drugs); *cf. McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 405 (S.D.N.Y. 2014) ("courts have refused to graft onto the adequacy standard a requirement that a package insert must include specific adverse event frequencies"); *Pauley v. Bayer Corp.*, No. 2681 EDA 2005, 2009 WL 1654592, at *3 (Pa. Super. Ct. June 12, 2009) (affirming lower court's ruling that no evidence should be presented to jury based on either AER data or comparative AER data that adverse events occurred more frequently with defendant's drug than with other drugs "because AERs are generally unreliable and not scientifically verified").

appropriate on Plaintiff's failure to warn claim.

B. Plaintiff's Consumer Fraud Claim (Count XIV) Fails Because She Cannot Prove Any of the Required Elements.

In her short form complaint, Plaintiff alleges "Violations of Applicable Georgia Law Prohibiting Consumer Fraud and Unfair and Deceptive Trade Practices." Although Plaintiffs' Master Complaint does not reference the applicable Georgia statute, "[t]o prevail on a private claim under the [Fair Business Practices] Act, a plaintiff must establish three elements: violation of the Act, causation, and injury. But an FBPA plaintiff must also comply with the ante litem requirement of OCGA § 10–1–399(b)." *Alvear v. Sandy Springs Toyota, Inc.*, 332 Ga. App. 798, 803, 775 S.E.2d 172, 177 (2015) (internal quotations omitted). Plaintiff has put forth no evidence of any misrepresentation made to Dr. Avino, any reliance on a misrepresentation by Dr. Avino, or that she has met any of the other requirements, such as ante litem notice, for a FBPA claim. As such, her claim should be dismissed. *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM, 2016 WL 4844442, at *11 (N.D. Ga. Mar. 24, 2016) ("Once again, Plaintiff's allegations amount merely to restating the elements of the cause of action without any factual support. Plaintiff pleads merely that Defendants violated the consumer protection laws through the use of false and misleading misrepresentations. In doing so, Plaintiff provides no factual support for that legal conclusion.").

C. Plaintiff's Negligence *Per Se* Claim (Count IX) Fails Because Plaintiff Has Failed to Provide Any Evidence that Bard Violated a State Safety Statute and Any Alleged Violation of the FDCA Would Be Preempted By Federal Law.

Under Georgia law, "a defendant is considered negligent per se based upon violation of a statute if there is evidence that the defendant violated the statute, the injured person was in the class the statute was intended to protect, the injured person suffered the type of harm the statute intended to guard against, and the alleged negligence per se proximately caused the injuries." *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011). However, "a private litigant cannot

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bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). This is because "no privatswze right of action exists for a violation of the FDCA." *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001); 21 U.S.C. § 337(a).

Plaintiff has failed to allege or produce evidence showing that Bard violated any state safety statute. Instead, Plaintiff alleges that Bard violated the FDCA by marketing an adulterated and misbranded device. Plaintiff's "claim of negligence per se would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law." *Leonard*, 2011 WL 3652311, at *8. To the extent that Plaintiff's claim is only founded upon an alleged violation of the FDCA or related FDA regulations, such claim should be impliedly preempted. *Id.* (finding negligence per se claim impliedly preempted by § 337(a) because "Plaintiffs cannot create a private right of action under the guise of a state law claim."). Since Plaintiff has provided no evidence of a violation of a state safety statute, and reliance on any alleged violation of the FDCA would be impliedly preempted by federal law, Bard is entitled to summary judgment.

D. Plaintiff Has Offered No Evidence Sufficient To Bring a Punitive Damages Claim.

Plaintiff's punitive damages claim is without merit under Georgia law and must be dismissed. As a preliminary matter, under Georgia law, a plaintiff has no right to punitive damages, which are only assessed in extreme cases. *Roberts v. Forte Hotels, Inc.*, 227 Ga. App. 471, 472, 489 S.E.2d 540, 542 (1997). To authorize punitive damages, Plaintiff must show clear and convincing evidence of "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of a conscious indifference to the consequences" of the tortious act. O.C.G.A. § 51-12-5.1(b). "Conscious indifference to consequences means an intentional disregard of the rights of

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another, knowingly or willfully;" indeed, under Georgia law, even clear and convincing evidence of gross negligence will not support an award of punitive damages. *COMCAST Corp. v. Warren*, 286 Ga. App. 835, 838-39, 650 S.E.2d 307, 311 (2007).

Moreover, a manufacturer's "compliance with county, state, and federal regulations is not the type of behavior which supports an award of punitive damages," and, "as a general rule," punitive damages are "improper where a defendant [in a products liability case] has adhered to . . . safety regulations." *Stone Man, Inc. v. Green*, 263 Ga. 470, 472, 435 S.E.2d 205, 206 (1993). "This is because 'such compliance does tend to show that there is no clear and convincing evidence of 'willful misconduct, malice, fraud, oppression, or that entire want of care which would raise the presumption of [a] conscious indifference to [the] consequences.'" *Barger v. Garden Way, Inc.*, 231 Ga. App. 723, 728, 499 S.E.2d 737, 743 (1998). While compliance with safety regulations does not automatically preclude punitive damages if "there is other evidence showing culpable behavior," to survive summary judgment, Plaintiff still "must present some evidence of 'willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences.'" *Edwards v. Ethicon, Inc.*, 30 F. Supp. 3d 554, 564 (S.D. W. Va. 2014) (citations omitted) (applying Georgia law and granting summary judgment on punitive damages claim).

Here, punitive damages are not warranted because there is no evidence that Bard acted with the malice, fraud, wantonness, oppression, or entire want of care necessary to sustain an award of punitive damages. O.C.G.A. § 51-12-5.1(b). Instead, Bard complied with applicable FDA regulations in bringing the Filter to market, resulting in the Filter being cleared by the FDA through the 510(k) process outlined in the FDCA for retrievable use on January 14, 2010. (SSOF, ¶ 24); *see* 21 U.S.C. § 360e(b)(1)(B) (establishing 510(k) clearance); 21 C.F.R. 807.87 (outlining process for 510(k) clearance application); *see generally* Defendants' Motion for Summary Judgment Regarding Preemption (Doc. 5396). Bard also complied with applicable regulations in the Filter's labeling. Furthermore, there is no evidence in this case that Bard intentionally disregarded

Plaintiff's rights, which is necessary to show a "conscious indifference to consequences," *COMCAST*, 286 Ga. App. at 839, 650 S.E.2d at 311, or that Bard specifically acted with the purpose of causing damage and loss. Because Plaintiff cannot offer evidence that Bard acted deliberately and with malice with regard to Plaintiff, or with an entire want of care, her punitive damages claim must fail.

VI. Conclusion.

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Partial Summary Judgment.

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

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